

SENSODYNE REPAIR AND PROTECT- stannous fluoride paste
SENSODYNE REPAIR AND PROTECT EXTRA FRESH- stannous fluoride paste
SENSODYNE REPAIR AND PROTECT WHITENING- stannous fluoride paste
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Stannous fluoride 0.454% (0.15% w/v fluoride ion)

Purposes

Anticavity, Antihypersensitivity

Uses

- aids in the prevention of dental cavities.
- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact.

Warnings

Stop use and ask a dentist if

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- pain/sensitivity still persists after 4 weeks of use.

Keep out of reach of children.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 12 years of age and older:**
 - apply at least a 1-inch strip of the product onto a soft bristle toothbrush.
 - brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times a day, or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.

- **children under 12 years of age:** Consult a dentist or doctor.

Other information

- products containing stannous fluoride may product surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.
- this product is specifically formulated to help prevent staining.
- store below 25°C (77°F)

Inactive ingredients (Regular)

glycerin, PEG-8, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, polyacrylic acid, silica, cocamidopropyl betaine, sodium saccharin

Inactive ingredients (Extra Fresh)

glycerin, PEG-8, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, polyacrylic acid, silica, sodium saccharin, cocamidopropyl betaine

Inactive ingredients (Whitening)

glycerin, PEG-8, hydrated silica, pentasodium triphosphate, flavor, sodium lauryl sulfate, titanium dioxide, polyacrylic acid, silica, cocamidopropyl betaine, sodium saccharin

Questions or comments?

Call toll-free **1-866-844-2797**

Principal Display Panel

NDC 0135-0548-02

SENSODYNE

FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

new

IMPROVED FOAMING ACTION

#1 DENTIST RECOMMENDED BRAND

MINT

REPAIR & PROTECT

DEEP REPAIR

NET WT 3.4 OZ (96.4 g)

SENSODYNE REPAIR & PROTECT DEEP REPAIR

Sensodyne Repair & Protect has a clinically proven ingredient. With twice daily brushing it helps to repair deep inside the tubules and relieves sensitivity to help you enjoy life without worrying about the pain of sensitive teeth.

EXPOSED DENTIN; CAUSE OF SENSITIVE TEETH

TINY HOLES

GETS DEEP INSIDE THESE HOLES

TO HELP REPAIR THESE HOLES

WHICH HELPS PROTECT FROM PAIN*

Daily use fluoride toothpaste to provide long lasting sensitivity relief, whilst also keeping your teeth and gums healthy. *

*with twice daily brushing

ALWAYS FOLLOW THE LABEL

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Distributed by:

GSK Consumer Healthcare

Warren, NJ 07059

62000000057489 Carton Front



Principal Display Panel

NDC 0135-0547-02

SENSODYNE

FLUORIDE TOOTH PASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

new

IMPROVED FOAMING ACTION

#1 DENTIST RECOMMENDED BRAND

EXTRA FRESH

REPAIR & PROTECT

DEEP REPAIR

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GSK Consumer Healthcare

Warren, NJ 07059

62000000057437 Carton Front



Principal Display Panel

NDC 0135-0575-01

SENSODYNE

FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH AND CAVITY PREVENTION

new

IMPROVED FOAMING ACTION

#1 DENTIST RECOMMENDED BRAND

WHITENING

REPAIR & PROTECT

DEEP REPAIR

NET WT 3.4 OZ (96.4 g)

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GSK Consumer Healthcare

Warren, NJ 07059

62000000057397 Carton Front

new

IMPROVED
FOAMING ACTION

NDC 0135-0575-01

#1 DENTIST RECOMMENDED BRAND

SENSODYNE

FLUORIDE TOOTHPASTE FOR SENSITIVE TEETH
AND CAVITY PREVENTION

WHITENING

REPAIR
& PROTECT

DEEP REPAIR




NET WT 3.4 OZ (96.4 g)

SENSODYNE REPAIR AND PROTECT

stannous fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0548
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM TRIPOLYPHOSPHATE, UNSPECIFIED FORM (UNII: 5HK03SA80J)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0548-02	1 in 1 CARTON	06/28/2021	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0135-0548-01	1 in 1 CARTON	06/28/2021	
2		23 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/28/2021	

SENSODYNE REPAIR AND PROTECT EXTRA FRESH

stannous fluoride paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0547
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM TRIPOLYPHOSPHATE, UNSPECIFIED FORM (UNII: 5HK03SA80J)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	

Flavor		MINT	Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0547-02	1 in 1 CARTON	06/28/2021	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part356	06/28/2021	

SENSODYNE REPAIR AND PROTECT WHITENING

stannous fluoride paste

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0135-0575
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	1.10 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			
SODIUM TRIPOLYPHOSPHATE, UNSPECIFIED FORM (UNII: 5HK03SA80J)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0135-0575-01	1 in 1 CARTON	06/28/2021	
1		96.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/28/2021	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 3/2021

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC